Brighton & Hove City Council

NHS Brighton and Hove Clinical Commissioning Group

PATIENT GROUP DIRECTION

Doxycycline for the treatment of uncomplicated genital chlamydia trachomatis infection

For the supply of **Doxycycline 100mg on Patient Group Direction (PGD)** by **community pharmacists working in** Brighton and Hove and contracted to provide treatment for chlamydia trachomatis infection as part of the locally commissioned Sexual Health and Contraceptive Service.

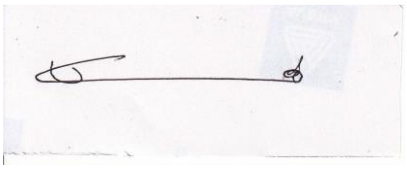
Direction no: BH 2018 11

CHANGE HISTORY	
Version/Date	Change details
BH 2018 11	Updated Summary of Product Characteristics (SmPC) Updated National Institute for Health and Care Excellence (NICE) Guidance Updated British Association for Sexual Health and HIV (BASHH) guidelines

PGD comes into effect	1st January 2021
PGD review date	1st January 2022
PGD expiry date	31st December 2022

Valid from: 1/1/21
Review date: 1/1/22
Expiry date: 31/12/22
Approving Organisation: BHCC

This PGD template has been developed by the following health professionals on behalf of Brighton & Hove City Council (BHCC):

NAME/ROLE	SIGNATURE	DATE
Clinical Lead for Medicine Management Dr Will Shepherd		01/12/2020
Pharmacist Janet Rittman		16/11/20
Chief Nursing Officer & Caldicott Guardian Allison Cannon		08/12/2020

ORGANISATIONAL APPROVAL

The PGD is not legally valid until it has had the relevant organisational approval.

It is the responsibility of the organisation that has legal authority to authorise the PGD to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

Patient Group Direction authorised by:		
TITLE /ORGANISATION	**SIGNATURE**	**DATE**
Alistair Hill Director of Public Health Brighton and Hove Council		01/01/21

Valid from: 1/1/21
Review date: 1/1/22
Expiry date: 31/12/22
Approving Organisation: BHCC

This Patient Group Direction (PGD) must only be used by accredited community pharmacists who have been named and authorised by their organisation to practise under it. The most recent and in date final signed version of the PGD must be kept in a designated place within the pharmacy and be readily accessible to all community pharmacists for reference and audit.

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the General Pharmaceutical Council (GPhC) Standards for Pharmacy Professionals and Pharmaceutical Society of Northern Ireland (PSNI) Code of Ethics for Pharmacists.

No PGD can envisage every clinical situation. Pharmacists are expected to exercise professional judgement and discretion. In any situation where there is a concern a doctor must be consulted.

Individual practitioners must declare that they have read and understood the PGD and agree to supply or administer medicines in accordance with the PGD criteria within the specified start and expiry dates.

The pharmacist must work within the service specification agreed between the employing pharmacy and the commissioning organisation.

Patient group direction effective from 1st January 2021
PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD
BHCC authorises the use of this document by accredited community pharmacists who are working within the boundaries of Brighton & Hove
DECLARATION: I am a registered pharmacist, employed at

Name of Pharmacy	
Address	
Post Code	

User confirmation

Patient group direction effective from 1st January 2021
PROFESSIONALS AUTHORISED TO SUPPLY UNDER THIS PGD
BHCC authorises the use of this document by accredited community pharmacists who are working within the boundaries of Brighton & Hove City Council.
DECLARATION: I am a registered pharmacist, employed at

Name of Pharmacy	
Address	
Post Code	

I have read this Patient Group Direction (PGD) and confirm that:
Qualifications • I am registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI) • I am employed within a community pharmacy commissioned to provide the Sexual Health and Contraceptive Service Specification. **Specialist qualifications and competencies** • I have completed the accreditation and training requirements detailed in the Sexual Health and Contraceptive Service Specification. • I have completed the **Emergency Contraception** and **Chlamydia Testing and Treatment Service** Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website https://www.cppe.ac.uk/services/declaration-of-competence • Pharmacists' personalised statement of declaration should be retained, which may need to be provided to commissioners and/or employers when required via the CPPE Viewer. • I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment. • I am aware of local safeguarding policies and contact information. • I have reviewed the local policies and documentation for this service and references associated with this PGD. • I am aware that it is my responsibility to keep up to date with changes to the recommendations for this medicine and acknowledge any limitations to my knowledge or competence. I will complete continuing professional

development as defined by the GPhC or PSNI and take part in an audit as detailed in the service specification.

Name	GPhC/PSNI registration number	Signature	Date

Signature of Authorising Pharmacist or Pharmacy Manager

…….

Name of Authorising Pharmacist or Pharmacy Manager

…….

1. Clinical conditions or situation to which this Patient Group Direction applies

1.1 Definition of clinical situation for use	The supply of doxycycline 100mg for the treatment of uncomplicated genital Chlamydia trachomatis infection.
1.2 Criteria for inclusion	• Individual (index patient) or sexual contact of individual with a positive, asymptomatic diagnosis of genital chlamydia trachomatis infection evidenced by contact slip, text message or other written confirmation from the Chlamydia Screening Programme (CSP). • Individuals who have had sexual intercourse with an untreated sexual contact within 7 days of starting treatment. • Individuals or sexual contact of individual who did not complete the 7-day treatment course. • Individual or sexual contact of individual must be able to give **informed consent** to treatment. Informed consent is the process by which an individual learns about and understands the purpose, benefits, and potential risks of a treatment and then agrees to receive the treatment. • If the individual is under 16 years old, they must be assessed as Fraser competent (see Appendix 1) or if not assessed as Fraser Competent accompanied by one or both parents, or a legal guardian and consents to the treatment being given. • Individual consents to consultation and medication supply by a pharmacist without referral to a doctor.
1.3 Criteria for exclusion	**Personal Characteristics** • Individuals aged under 16 years who are assessed as **not** competent using Fraser Guidelines. • If under 13 years of age follow the local safeguarding children policy. • Individual without capacity to consent. • Individual wishes to see a doctor. • Safeguarding or child sexual exploitation (CSE) concerns- refer to section 1.5. **Medical History** • Suspected complicated chlamydia infection. • Individual is pregnant or breastfeeding. • Hepatic impairment or those receiving potentially hepatotoxic drugs. • Severe renal impairment. • Presence of urinary symptoms. • Presence of penile discharge, epididymitis or testicular pain in men. • Presence of vaginal discharge in women. • Presence of concomitant conjunctivitis and /or joint pain/swelling.

	• Fever. • Females with pelvic pain or suspected pelvic Inflammatory Disease (PID). • Porphyria. • Known Myasthenia Gravis. • Individual is being treated for HIV. • Known Systemic Lupus Erythematosis. • Individuals with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take doxycycline. **Medication History** • Known allergy or hypersensitivity to Doxycycline or other tetracycline antibiotics (refer to a current BNF for the full list) or any constituent of the medication refer to section 6.1 of the Summary of Product Characteristics (SmPC). • Individual taking an interacting medicine. **See section 2.11.**
1.4 CAUTIONS: Need for further advice or action to be taken	• The use of drugs of the tetracycline class during tooth development (pregnancy, infancy and childhood to the age of 12 years) may cause permanent discolouration of the teeth (yellow-grey-brown). See section 4.3 of SmPC for further information. • Doxycycline is contraindicated in **pregnancy**. The risks associated with the use of tetracyclines during pregnancy are predominantly due to effects on teeth and skeletal development. • Tetracyclines are excreted into milk and are therefore contraindicated in nursing mothers. (see above about use during tooth development). • Individuals likely to be exposed to direct sunlight or ultraviolet light (sun lamps) should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema and to contact the Sexual Health and Contraceptive service (SHAC) for further advice. • Visual disturbances such as blurring of vision may occur during treatment with doxycycline and in such cases; individuals must refrain from driving or operating machinery. • Sexual contacts of the index patient treated under the PGD should be encouraged to consent to their telephone number being shared with the CSP, to enable contact tracing and a follow-up to the treatment. Information shared will be treated confidentially. If the individual does not consent to sharing the information, treatment can still be provided. • Sexual contacts of the index patient treated under the PGD should be encouraged to complete a chlamydia test before starting treatment. The test should be completed on

	the day of the consultation so that treatment can start immediately. See section 2.12.
1.5 Action to be taken if the individual is excluded or declines treatment	• Signpost/refer to Sexual Health and Contraception (SHAC) service or GP as soon as possible with information about further options. Link to SHAC website http://brightonsexualhealth.com • If complicated chlamydia infection or other sexually transmitted infection (STI) suspected refer to SHAC. • A Best Interest assessment should be undertaken by an authorised prescribing practitioner for individuals who lack capacity to consent. http://www.legislation.gov.uk/ukpga/2005/9/contents • If child is < 13 years follow the local safeguarding children policy. • **Safeguarding** (including child sexual exploitation) concerns identified at presentation should be referred to the Brighton and Hove Safeguarding Children Partnership (BHSCP) https://www.brightonandhovelscb.org.uk/wp-content/uploads/BH-Safeguarding-Children-Partnership-Arrangements-Final.pdf. • Follow local safeguarding arrangements for vulnerable adults when appropriate. https://www.brighton-hove.gov.uk/adult-social-care/keep-people-safe/help-adult-risk-abuse-or-neglect. • If the individual declines treatment discuss implications, record the declination on PharmOutcomes and inform the CSP. • Document all actions taken.

2. Description of Treatment

2.1 Name, strength & formulation of drug	Doxycycline 100mg capsules
2.2 Legal status	Prescription only medicine (POM)
2.3 Storage of products	Medicines must be stored securely according to national guidelines and in accordance with the Summary of Product Characteristics(SmPC) https://www.medicines.org.uk/emc/product/4063/smpc#gref
2.4 Off label use	This medicine can only be supplied according to the SmPC. Drugs should be stored according to the conditions detailed in section 2.3. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with the pharmacy/Medicines Management.
2.5 Dose and frequency of administration	**Adults and young people over > 12years** 100mg twice a day for 7 days
2.6 Quantity	14 capsules
2.7 Route of administration	• Oral. • Take with plenty of fluid in either the resting or standing position and well before going to bed to reduce the likelihood of oesophageal irritation and ulceration. • If gastric irritation occurs, it is recommended that the capsule is taken with food or milk
2.8 Labelling requirements	• Label as per the legislation for a prescription only medicine (POM) • The patient information leaflet (PIL) must be given to the individual
2.9 Number of times treatment may be administered	Treatment can be provided once (excluding individuals that are reinfected before completing the 7-day treatment or who fail to complete the 7-day course (see Inclusion Criteria).

2.10 Identification & Management of Adverse Reactions	Refer to current Summary of Product Characteristics (SmPC) https://www.medicines.org.uk/emc/product/4063/smpc#gref and current British National Formulary (BNF) www.bnf.org for further information. **Common** • Abdominal pain, Nausea, vomiting, diarrhoea, oesophageal irritation. **Less common** • Loss of appetite. • Sore tongue.. • Rash caused by photosensitivity. • Sleep disturbance. • Confusion. • Hypersensitivity reactions and tinnitus. In the event of untoward or unexpected adverse reactions: If necessary seek appropriate emergency advice and assistance. Document in the individual patient medication record and complete incident procedure if adverse reaction is severe (refer to local organisational policy) Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at https://yellowcard.mhra.gov.uk/ The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
2.11 Drug interactions	**Refer to these sources of information for the full list of drug interactions and for further information:** • Summary of Product Characteristics (SmPC) https://www.medicines.org.uk/emc • British National Formulary (BNF) - current edition Appendix 1 or https://www.bnf.org • Stockley's Drug Interactions https://about.medicinescomplete.com/publication/stockleys-drug-interactions/ **Interacting medicines**- Examples are included below. • Medicines that induce hepatic enzymes such as phenobarbital, carbamazepine, primodone, and phenytoin.

	• Drugs that induce hepatic enzymes such as rifampicin. • Warfarin. There have been reports of prolonged prothrombin time in patients taking warfarin and doxycycline. • Methoxyflurane. The concurrent use of tetracyclines and methoxyflurane has been reported to result in fatal renal toxicity. See section 4.5 of SPC. • Ciclosporin. Doxycycline may increase plasma concentrations. • Methotrexate. Increased risk of methotrexate toxicity. • Retinoids, concomitant use should be avoided. • The absorption of doxycycline may be impaired by concurrently administered antacids containing aluminium, calcium, magnesium or other drugs containing these cations; oral zinc, iron salts or bismuth preparations. If necessary, access the individuals **NHS Summary Care Record (SCR)** (with consent) if they are uncertain about the medications they are taking.
2.12 Written information and further advice to be provided	• Discuss confidentiality and how information will be shared with the CSP. • Advise to swallow the capsules whole with plenty of fluids after food, while sitting or standing and well before bedtime to prevent irritation to the oesophagus. • Advise to space doses evenly throughout the day and to keep taking until the 7-day course is finished. • Refer to the PIL and advise individual to read it before starting treatment. • Inform individual of possible side effects and their management. • Individuals should be advised that they will not be clear of chlamydia until the 7-day treatment course has been completed. • Sexual contact (including oral sex) with partner should be avoided until partner has also completed the 7-day treatment course. • Do not take indigestion remedies concurrently – avoid antacids and calcium, magnesium and iron salts two hours before and one hour after taking doxycycline. • Individuals likely to be exposed to direct sunlight or ultraviolet light should be advised that this reaction can occur with tetracycline drugs and treatment should be discontinued at the first evidence of skin erythema. Individuals should be advised to avoid exposure to sunlight or sun lamps.

	• Individuals known to be taking part in high-risk sexual activity should be treated and advised to consult SHAC or GP. • Individuals that develop unusual or persistent side effects or symptoms of sexually transmitted infections should be referred to SHAC or their GP. • Advise individuals (index patient) that the CSP will contact them in 7 days to review the treatment and to discuss partner notifications. Sexual partners in the last 6 months will need to have testing and treatment. • Individuals treated as a sexual contact of an index patient should be given a chlamydia test and advised to complete and return (postal return) to the CSP before starting the treatment. The test should be completed on the day of the consultation so that treatment can start immediately. • Refer individuals to the Family Planning Association website for further information and a patient information leaflets on chlamydia https://www.fpa.org.uk/sites/default/files/chlamydia-information-and-advice.pdf • Give the individual a CSP treatment information pack (includes chlamydia test, condoms and SHAC contact information).
Advice/follow-up treatment	• Advise all individuals treated to retest for chlamydia in 3 months.
Records	Record the consultation and clinical assessment as prompted on the Pharmoutcomes (PO) chlamydia treatment template, including additional notes on the patient medication record (PMR) when necessary. The Pharmoutcomes template will record the following information: • Informed consent of the individual (index patient or sexual contact. • Safeguarding referral if relevant. • Name, DOB, CSP index code, telephone number. • If individual is under 16 years of age document competency using Fraser guidelines • If individual is under 13 years of age record action taken. • Drug name, manufacturer of product, batch number and expiry date of product. • Dose and quantity supplied. • Date supplied and by whom. • Advice given to individual (including side effects). • Whether sexual contact was treated today.

	• Confirmation that advice was given to abstain from all sexual contact until the 7-day treatment is finished. • Details of any adverse drug reaction and action taken. • Any referral arrangements. All records will be kept for 10 years after last attendance, or up to the patient's 26th birthday if longer than 10 years away. Records are subject to audit within each pharmacy.

3. Staff Group

3.1 Authorised staff	**Qualifications** 1. I am registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI). **2.** I am employed within a community pharmacy commissioned to provide the Sexual Health and Contraceptive Service Specification. **Specialist qualifications and competencies** 3. I have completed the accreditation and training requirements detailed in the Sexual Health and Contraceptive Service Specification. 4. I have completed the **Emergency Contraception** and **Chlamydia Testing and Treatment Service** Declaration of Competence (DoC) on the Centre for Pharmacist Postgraduate Education (CPPE) website https://www.cppe.ac.uk/services/declaration-of-competence. 5. Pharmacists' personalised statement of declaration should be retained, which may need to be provided to commissioners and/or employers when required via the CPPE Viewer. 6. I have completed the mandatory CPPE Safeguarding Children and Vulnerable Adults e-learning and passed the associated level 2 assessment. 7. I am aware of local safeguarding policies and contact information. 8. I have reviewed the local policies and documentation for this service and references associated with this PGD. 9. I am aware that it is my responsibility to keep up to date with changes to the recommendations for this medicine and acknowledge any limitations to my knowledge or competence. I will complete continuing professional development as defined by the GPhC or PSNI and take part in an audit as detailed in the service specification.

5. References

1. British Association for Sexual Health and HIV (BASHH) guidelines for the management of infection with Chlamydia trachomatis 2015 (updated 26 September 2018) https://www.bashh.org/guidelines
2. National Institute for Health and Care Excellence (NICE) Patient Group Directions (March 2017)
3. https://www.nice.org.uk/Guidance/MPG2
4. The Faculty of Sexual and Reproductive Healthcare (FSRH): Service Standards for Confidentiality in Sexual and Reproductive Health Services (2020) https://www.fsrh.org/news/fsrh-publishes-updated-service-standards-for-consultations-in/
5. British National Formulary(BNF) https://www.bnf.org/products/bnf-online/
6. Summary of product characteristics (SmPC) for Doxycycline 100mg Capsules
7. https://www.medicines.org.uk/emc/product/4063/smpc
8. The Pharmaceutical Society of Northern Ireland (PSNI), The code of ethics for pharmacists in Northern Ireland http://www.psni.org.uk/about/code-of-ethics-and-standards/
9. General Pharmaceutical Council: Standards for Pharmacy Professionals May 2017 https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf
10. Centre for Postgraduate Pharmacist Education (CPPE) Declaration of Competence. https://www.cppe.ac.uk/services/declaration-of-competence

Appendix 1

Under 16s- Fraser Guidelines

While the Fraser Guidelines below relate specifically to contraceptive advice or treatment, the principles are applicable to other sexual health services for young people under 16. A young person's age should not be a barrier to them accessing condoms.

A young person is competent to consent to contraceptive advice or treatment if:

- The young person understands the treatment, its purpose and nature, and why it is being proposed.
- The young person understands the benefits and risks of treatment and alternatives.
- The young person understands the professional's advice.
- The professional cannot persuade the young person to inform their parents or allow the professional to inform the parents that he or she is seeking advice.
- The young person is very likely to begin or continue having intercourse with or without the contraceptive treatment.
- Unless he or she receives contraceptive advice or treatment, the young person's physical or mental health or both are likely to suffer.
- The young person's best interests require the professional to give contraceptive advice, treatment or both without parental consent.

Reference

Faculty of Sexual and Reproductive Healthcare: Clinical Effectiveness Unit. March 2010 (Amended May 2019)

Contraceptive Choices for Young People.

https://www.fsrh.org/standards-and-guidance/documents/cec-ceu-guidance-young-people-mar-2010/